

## 510(k) Summary

**Company** Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, OH 45242

**Contact** Glenda Marsh  
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Ethicon Endo-Surgery, Inc.  
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MAR 25 2010

**Date Prepared** December 16, 2009

### **New Device Name**

Trade Name: Ethicon Endo Surgery® Slotted Anoscope

Common or Usual Name: Slotted Anoscope

Classification Name: Anoscope and accessories (21 CFR 876.1500, Product Code FER)

### **Predicate Device**

Sapimed Self Light Disposable Anoscope, model A.4083 (K070913)

**Device Description** The Ethicon Endo Surgery® Slotted Anoscope consists of a transparent plastic disposable anoscope in sterile condition. The Slotted Anoscope comprises a cylindrical body, with a closed end conical-shaped distal tip and a longitudinal open channel that accommodates a removable slide. The removable slide comprises a longitudinal open channel of 11mm in width. The body of the Slotted Anoscope has an outer diameter (OD) of 34mm. The Slotted Anoscope is a single patient use device.

The transparent characteristics of the material used in the Slotted Anoscope allows for visualization of the tissue in contact with the device in the anal canal. The opening in the removable slide provides access to tissue in the canal. The removal of the slide provides a wider margin of access to the targeted area.

**Indications for Use** The Ethicon Endo-Surgery® Slotted Anoscope has the same indication statement as the predicate device. The Slotted Anoscope is intended for physician use to examine the anal sphincter and anus, and using additional accessories, to perform various diagnostic and therapeutic procedures.

**Technological Characteristics** The EES Slotted Anoscope device the same technological characteristics to the predicate device in that it consists of a clear, transparent plastic anoscope of cylindrical shape and a closed, rounded (or conical) tip.

The only minor difference between the EES Slotted Anoscope and the predicate device is the width of the open channel (or tissue aperture). The new EES device contains a removable slide that provides the user with the choice of two different widths for the open channel. This difference does not affect the safety or performance characteristics of the new EES device compared to the predicate.

**Performance Data** Bench testing and preclinical laboratory evaluations were performed to demonstrate that the device performs as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Ms. Glenda Marsh  
QS/RA Senior Project Manager  
Ethicon Endo-Surgery, Inc  
4545 Creek Rd.  
CINCINNATI OH 45242

MAR 25 2010

Re: K093896

Trade/Device Name: Ethicon Endo Surgery® Slotted Anoscope  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FER  
Dated: March 4, 2010  
Received: March 8, 2010

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

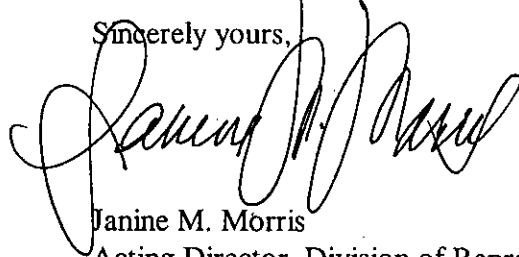
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name.

Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K093896

Device Name: Ethicon Endo Surgery® Slotted Anoscope

Indications for Use:

The EES Slotted Anoscope is intended for physician use to examine the anal sphincter and anus, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

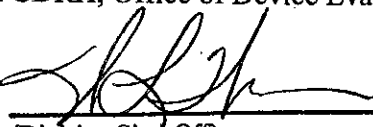
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K093896